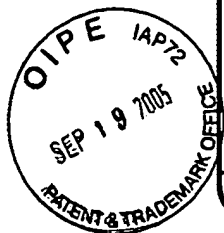


☒

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**Complete if Known**

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

Sheet

1

of

3

Application Number

10/696.011

Filing Date

**10-29-2003**

**First Named Inventor**

BERCHTOLD, et. al.

### Group Art Unit

~~1040~~ 1656

**Examiner Name**

~~Not Yet Assigned~~ NOAKES

Attorney Docket Number

DEAV2002/0069 - US - NP

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	78
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
Sm		EP	0 214 826		BRANGE, et. al.	03-18-1987		
		EP	0 375 437		BALSCHMIDT, et. al.	06-27-1990		
		EP	0 419 504		BRANGE, et. al.	04-03-1991		
		EP	0 678 522		DIMARCHI, et. al.	10-25-1995		
		EP	0709395		BAKER, et. al.	05-01-1996		
		WO	02/076495		BODERKE, et. al.	10-03-2002		
		WO	98/42749		HAVELUND, et. al.	10-01-1998		

**Examiner  
Signature**

Suzanne M. Nowkes

Date \_\_\_\_\_

[illegible]

22 Feb. 2006

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

Please type a plus sign (+) inside this box → ☒

PTO/SB/08B (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/696,011
		Filing Date	10-29-2003
		First Named Inventor	BERCHTOLD, et. al.
		Group Art Unit	1646 1656
		Examiner Name	Not Yet Assigned ADAKES
		Attorney Docket Number	DEAV2002/0069 - US - NP
Sheet	2	of	3

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Smu		BAKER, E.N., et. al., The Structure Of 2Zn Pig Insulin Crystals At 1.5 A Resolution, Phil. Trans. R. Soc. Land, (1998), Vol. 319, pp. 369 - 456	
		BENTLEY, G.A., et. al., Role Of B13 Glu In Insulin Assembly; The Hexamer Structure Of Recombinant Mutant (B13 Glu Gln) Insulin, Journal Of Molecular Biology, (1992), Vol. 228, pp. 1163 - 1176	
		BERGER M., et. al., Towards More Physiological Insulin Therapy In the 1990s, Diabetes Research and Clinical Practice, (1989), Vol. 6, pp. S25 - S31	
		BERNSTEIN, F.C., et. al., The Protein Data Bank: A Computer-Based Archival File For Macromolecular Structures, Journal Of Molecular Biology, (1977), Vol. 112, pp. 535 - 542	
		BOLLI, G.B., et. al., The Pharmacokinetic Basis Of Insulin Therapy In Diabetes Mellitus, Diabetes Research and Clinical Practice, (1989), Vol. 6, pp. S3 - S16	
		BRANGE, J., et. al., Neutral Insulin Solutions Physically Stabilized By Addition Of Zn2+, Diabetic Medicine, (1986), Vol. 3, pp. 532 - 536	
		DIXON, G.H., et. al., Regeneration Of Insulin Activity From The Separated And Inactive A and B Chains, Nature, (1960), Vol. 188, No. 4752, pp. 721 - 724	
		DRURY, P.L., et. al., Diabetic Nephropathy, British Medical Bulletin, (1989), Vol. 45, No. 1, pp. 127 - 147	
		HOME, P.D., et. al., Insulin Treatment: A Decade Of Change, British Medical Bulletin, (1989), Vol. 45, No. 1, pp. 92 - 110	
		KANG, S., et. al., Subcutaneous Insulin Absorption Explained By Insulin's Physicochemical Properties Evidence From Absorption Studies Of Soluble Human Insulin And Insulin Analogues In Humans, Diabetes Care, (1991), Vol. 14, No. 11, pp. 942 - 948	

Examiner Signature	<i>Lynne M. Noakes</i>	Date Considered	22 Feb 2006
--------------------	------------------------	-----------------	-------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☒

PTO/SB/088 (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/696,011
		Filing Date	10-29-2003
		First Named Inventor	BERCHTOLD, et. al.
		Group Art Unit	1646 116516
		Examiner Name	Not Yet Assigned <b>NOAKES</b>
Sheet	3	of	3
		Attorney Docket Number	DEAV2002/0069 - US - NP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
gmm		KEMMLER, W., et. al., Studies On The Conversion Of Proinsulin To Insulin, The Journal Of Biological Chemistry, (1971), Vol. 246, No. 22, pp. 6786 - 6791	
		KOHNER, E.M., et. al., Diabetic Retinopathy, British Medical Bulletin, (1989), Vol. 45, No. 1, pp. 148 - 173	
		MARSHALL, R.C., et. al., Protein Oligomer Composition, Preparation of Monomers and Constituent Chains, Practical Protein Chemistry - A Handbook (1986) S. 49-53	
		The Diabetes Control And Complications Trial Research Group, The Effect Of Intensive Treatment Of Diabetes On The Development And Progression Of Long-Term Complications In Insulin-Dependent Diabetes Mellitus, The New England Journal Of Medicine, (1993), Vol. 329, No. 14, pp. 977 - 986	
		WARD, J.D., et. al., Diabetic Neuropathy, British Medical Bulletin, (1989), Vol. 45, No. 1, pp. 111 - 126	

Examiner Signature	<i>Dwayne M. Noakes</i>	Date Considered	22 Feb. 2006
--------------------	-------------------------	-----------------	--------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.